EXHIBIT F

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	**D. CHRISTENSON**	OMHA Appeal No.:	**1-8630709341**
Beneficiary:	**D. CHRISTENSON**	Medicare:	**Part B**
Medicare No.:	***3639A**	Before:	**Scott M. Watson** Administrative Law Judge

DECISION

After carefully considering the evidence, arguments and testimony presented in the record, an **UNFAVORABLE** decision is entered against the Appellant/Beneficiary, D. Christenson.

Procedural History

The Appellant requested coverage under Medicare Part B of a tumor treatment field therapy (TTFT) device called Optune which was supplied by Novocure, Inc. (Provider) on November 13, 2018, December 3, 2018, and January 3, 2019. A claim for the device was submitted to a Medicare Administrative Contractor (MAC), which was denied initially and upon redetermination. On June 7, 2019, a Qualified Independent Contractor (QIC), C2C Solutions, Inc., issued an unfavorable reconsideration decision.

The Appellant timely filed a request for an Administrative Law Judge (ALJ) hearing. The amount in controversy meets the jurisdictional requirements for a hearing. See 42 C.F.R. §§ 405.1006 and 422.5600(b).

An administrative hearing was held by telephone on August 28, 2019. The Appellant was represented by Attorney Debra Parrish. Timothy Parks, RN, of Novocure also testified on behalf of the Appellant. The relevant CMS contractors were sent notice of the hearing but declined to participate.

All exhibits were admitted into evidence without objection.

Issue

The issue is whether Medicare Part B covers the TTFT device to assist with the treatment/management of the Appellant's recurrent glioblastoma.

Findings of Fact

The following facts are established by the preponderance of the evidence.

1. The Appellant, a 65-year old man, was diagnosed with gliobastoma ("GBM") in July 2015. He then underwent successful resection, chemotherapy, and radiation therapy to treat his GBM. But in early 2016, post-treatment studies showed a size increase in the GBM. The Appellant's physician ordered one year of TTFT in combination with temozolomide to treat the recurrent GBM. In February 2017, the Appellant began receiving only TTFT for his recurrent GBM. (Park's testimony; *See* also Appellant's pre-hearing brief)

2. On September 19, 2018, the Appellant underwent an MRI of the brain. The image showed that the tumor was stable. (Exh. 2, p. 20).

3. The appeal file includes a "Proposed Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (DL34823)" that states that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary for the treatment of *recurrent* GBM." (Exh. 5, p. 20).

4. The revised LCD L34823, with an effective date of September 1, 2019, expressly states that TTFT will be denied as not reasonable and necessary for treatment of *recurrent* GBM. The LCD also provides that the DME-MACs received a request to reconsider the decision on recurrent GBM in 2018; however, the requestor, Novocure, did not submit new evidence in support of the revised coverage for recurrent disease. The DME-MACs therefore concluded that the request was invalid.[1]

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an adverse organization determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1859(g)(5); see 42 C.F.R. § 422.600. The request for hearing is timely filed if filed within 60 days of the date of notice of a reconsidered determination. 42 C.F.R. § 422.602.

In implementing this statutory directive, the Secretary delegated authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals (OMHA). See 70 Fed. Reg. 36386, 36387 (June 23, 2005). ALJs within

[1] *See* https://med.noridianmedicare.com/documents/2230703/7218263/Tumor+Treatment+Field+Therapy+%28TTFT%29%20LCD+and+PA/8f195ce1-c8e1-4c92-8578-f2b8996e4507

OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

B. Scope of Review

Medicare Advantage Organization determinations and appeals are governed by the regulations in 42 C.F.R. §§ 422.560 through 422.626. Unless otherwise noted, the ALJ hearing procedures set forth in 42 C.F.R. §§ 405.1000 through 405.1064 apply to Medicare Advantage appeals, to the extent they are appropriate. 42 C.F.R. § 422.562(d).

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a). However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she may notify the parties before the hearing and may consider it an issue at the hearing. *Id.*

C. Standard of Review

The OMHA is staffed with ALJs who conduct de nova hearings. 42 C.F.R. § 405.1 OOO(d). A de novo review means the ALJ reviews the evidence without regard to the findings in the prior determinations on the claim and makes an independent assessment based on the evidence and the controlling laws. However, the burden of proving each element of a Medicare claim lies with the appellant and is satisfied by submitting sufficient evidence in accordance with Medicare rules. See e.g., Act §§ 1814(a)(l), 1815(b), and 1833(e); see also 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

Eligibility for Medicare benefits is determined under Title XVIII of the Act, 42 U.S.C. § 1801 et seq., and federal regulations set forth in Title 42 of the Code of Federal Regulations.

According to section 1862(a)(l)(A) of the Act, no payment may be made under Original Medicare for any expenses incurred for items or services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See 42 U.S.C. § 1395y(a)(l)(A); see also 42 C.F.R. § 41 1.15(k)(l).

B. Policy and Guidance

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination (NCD), can establish or change a substantive legal standard governing the scope of the benefits or payment for services under the Medicare program unless promulgated as a regulation by CMS. NCDs promulgated by the Secretary of HHS under the authority of Section 1862(a)(l) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. 42 C.F.R. § 405.1060(a)(4); see 42 C.F.R. § 405.1060(b)(l) ("An ALJ may not disregard, set aside or otherwise review an NCD").

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). 42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

The DME MAC with jurisdiction over this appeal applied LCD L34823 (Tumor Treatment Field Therapy (TTFT)). The applicable LCD provides that TTFT (E0766) will be denied as not reasonable and necessary.

Analysis

The Appellant seeks reimbursement for TTFT (E0766) to treat recurrent GBM. The QIC and the MAC denied the request because a Medicare local coverage determination states "[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary." (LCD L34823). For the reasons set forth below, I agree with the previous denial and conclude that Medicare Part B does not provide for coverage of TTFT for the treatment of the Appellant's recurrent GBM.

CMS has determined that the TTFT Optune device (E0766) meets the definition of durable medical equipment (DME). (See Policy Article A52711). Medicare covers DME when sufficient information is provided to conclude that the DME was medically reasonable and necessary for the treatment or management of an illness or medical condition. See Act § 1862(a)(1)(A). Generally, CMS and its contractors publish coverage policies and guidance to apply when considering whether or not certain DME is reasonable and necessary. See Act § 1869(f)(2)(B); 42 C.F.R. § 405.1060; *MPIM*, ch 13, § 13.5.1

In this case, the MAC and the QIC relied on LCD L34823 to support denial of the Appellant's request for coverage. The pertinent LCD provides conclusory language stating "[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary." The LCD does not elaborate further as to why TTFT is deemed not reasonable and necessary.

Since the publication of this LCD, the DME-MACs, through their medical directors, have conceded that LCD L34823 only precludes coverage of TTFT for ***recurrent*** GBM as not reasonable and necessary. The DME-MACs have explicitly stated that LCD L324823 does not address coverage for ***newly diagnosed*** GBM. However, the issue in this case pertains to coverage of TTFT for ***recurrent*** GBM, which is addressed by L34823. I therefore find that L34823 should be applied to find that TTFT for the treatment of recurrent GBM is considered not reasonable and necessary.

While I understand that this treatment has been effective for the Appellant since he began receiving the treatment, I am bound to follow Medicare rules and regulations. I find that there is not sufficient evidence to show that L34823 does not apply to the Beneficiary's diagnosis, nor is

there sufficient evidence to show that the LCD should be disregarded. Neither the old nor the revised LCD provides for coverage of TTFT for the treatment of recurrent GBM. Therefore, based upon the record, I find that the Appellant is not entitled to coverage of the Optune tumor treatment field therapy (E0766) received on November 13, 2018, December 3, 2018, and January 3, 2019.

Where the Medicare coverage requirements have not been met, waiver of liability pursuant to section 1879(a) of the Social Security Act, 42 U.S.C. § 1395pp(a), might apply. A provider will be held liable for the cost of services unless it did not know, and reasonably could not have known, that the services would not be covered. The same statutory provision applies to beneficiaries, although the "reasonably could not have known" standard is interpreted and applied differently in their case due to their presumed unfamiliarity with the numerous publications that govern Medicare coverage.

There was no Advance Beneficiary Notice ("ABN") included in the file. The Beneficiary neither knew, nor reasonably should have been expected to know, that services would not be covered by Medicare. Novocure ("Provider") is presumed to have knowledge of published Medicare coverage rules, regulations, and guidelines. The Provider either knew, or reasonably should have been expected to know, that the services denied would not be covered by Medicare. As a result, the Provider is not eligible for a waiver of liability, pursuant to § 1879 of the Act, 42 U.S.C. § 1395pp(a), and is liable for the non-covered charges.

Conclusions of Law

Medicare Part B does not cover the tumor treatment field therapy (E0766) for recurrent GBM; therefore, the Appellant is not entitled to coverage of the TTFT (E0776) provided to the Appellant on November 13, 2018, December 3, 2018, and January 3, 2019.

Novocure remains financially liable for the denied charges.

Order

The Medicare contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: SEP 12 2019

Scott M. Watson
Administrative Law Judge